

Application Serial No. 09/720,762

Attorney Docket No. 114474.00014

Amendment and Response to Non-Final Office Action, Submitted April 17, 2009

Claim 39 (previously presented): The gasket according to claim 33, wherein the pre-filled syringe further comprises a luer lock portion formed in a nozzle of the syringe at an end of the syringe barrel opposite the gasket.

Claim 40 (previously presented): The gasket according to claim 33, wherein a second tapered slant is formed between the peripheral side surface of the gasket that contacts the inner surface of the syringe barrel and the restriction.

Claim 41 (canceled).

REMARKS/ARGUMENTS

Claims 1, 3, 6-9, 11 and 13-40 are now pending, a total of 35 claims. Independent claims 1, 9, 23 and 33 are currently amended. Support for the amendments can be found, for example, on pages 3-5 of the specification as filed.

Dependent claims 2, 4, 5, 10, 12 and 41 have been canceled.

I. Claim Objections

Claims 1, 9, 23 and 33 were objected to because of the use of single brackets to indicate deleted subject matter. These claims have been amended using strikethrough to indicate the deleted subject matter in question. Applicant respectfully requests withdrawal of this objection.

II. Claim Rejections - 35 U.S.C. § 103

A. Claims 1, 3, 6-9, 16-28 and 30-32: Trull in view of Sudo

Claims 1, 3, 6-9, 16-28 and 30-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136) in view of Sudo et al. (U.S. 5,009,646).

Claim 1 is presently amended to recite as follows:

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1. Claim 1 (currently amended): A gasket for a pre-filled syringe, the syringe comprising a barrel composed of a polyethylene fiber into which liquid is charged,

wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, wherein the restriction has an inner diameter with a ratio of 0.8 or more and less than 1.0 to a diameter of the gasket, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin.

Neither Trull nor Sudo fairly teach or suggest a gasket for a pre-filled syringe with a barrel composed of a polyethylene fiber, with the gasket having the recited limitations of the present claim 1.

Trull does not teach or suggest a laminated gasket. Nor does Trull teach or suggest the desirability of a certain relationship between the diameter of a gasket and the diameter of an annular restriction of the gasket in order to obtain sufficient rigidity to avoid bending relative to the axis of the syringe barrel and prevent leakage. By contrast, the Trull reference teaches that the so-called "cocking" problem of prior art plungers is overcome by a driving head coupling arrangement whereby flexible resilient members at the plunger rear engage a driving head affixed to an injector. (col. 7, line 14 to col. 8, line 9; col. 11, lines 30-35). Nor does the Sudo reference teach or suggest a specific relationship between the diameters of the gasket and a restriction thereof.

Sudo also does not teach to selectively laminate a gasket as recited in amended claim 1, and Applicant respectfully disagrees that MPEP 2144.04(2)(a) is applicable in the

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present case. MPEP 2144.04(2)(a) is directed to the omission of separate and distinct elements. In contrast, Sudo teaches that the gasket is fully laminated, with the lamination of the peripheral side and the side contacting the fluid being formed from one piece simultaneously with the forming of the gasket (see, e.g., col. 3, lines 61-66). Thus, it would not be obvious to meet the limitations recited in the present claim 1 by modifying the laminated layer as taught in Sudo.

For at least the reasons discussed above, the cited references do not teach or suggest a laminated gasket with restriction with a syringe barrel composed of a polyethylene fiber as recited in amended claim 1.

Independent claims 9 and 23 are also presently amended to recite that "the syringe comprising a barrel composed of a polyethylene fiber...".

As discussed above, claims 9 and 23 stand rejected as being unpatentable over the Trull and Sudo references. However, Trull does not teach or suggest a laminated gasket. Neither Trull nor Sudo identify or describe desired dimensions of the plunger or a restriction thereof. Further, the Trull plunger / driving head arrangement teaches away from use of a restriction of the plunger to prevent bending. For at least the aforementioned reasons, the cited references do not teach or suggest a laminated gasket having a restriction with a syringe barrel composed of a polyethylene fiber as recited in amended claims 9 and 23.

It is respectfully submitted that dependent claims 3, 6-8, 16-22, 24-28 and 30-32 are patentable with the independent claims set forth above. These dependent claims recite additional features that further distinguish the invention.

B. Claims 14-15: Trull in view of Sudo and further in view of Akaike

Dependent claims 14-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull in view of Sudo and further in view of Akaike (U.S. 5,061,247). In light of the present amendments and arguments above, is respectfully submitted that these dependent claims are also patentable with their respective independent claims as set forth above, and recite additional features that further distinguish the invention.

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C. Claims 11, 13 and 29: Trull in view of Sudo and further in view of Higashikawa

Dependent claims 11, 13 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull in view of Sudo and further in view of Higashikawa (U.S. 5,830,193). In light of the present amendments and arguments above, it is respectfully submitted that these dependent claims are also patentable with their respective independent claims as set forth above, and recite additional features that further distinguish the invention.

D. Claims 33-40: Trull in view of Sudo and further in view of Vacca

Claims 33-40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull in view of Sudo and further in view of Vacca (U.S. 5,531,255).

Independent claim 33 is currently amended, and recites as follows:

33. Claim 33 (currently amended): A gasket for a pre-filled syringe, the syringe comprising a barrel composed of a polyethylene fiber into which liquid is charged,

wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, wherein the restriction has an inner diameter with a ratio of 0.8 or more and less than 1.0 to a diameter of the gasket, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with silicon.

Independent claim 33, as amended, is patentable over the cited references. As discussed above, Trull does not teach a laminated gasket with a syringe composed of

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polyethylene fiber, and Sudo does not teach or suggest selective lamination of a gasket. Neither does Vacca. And none of the cited references addresses the specific geometric limitations recited in the claims. For at least the reasons discussed above, the references of record do not teach or suggest applying silicon to a gasket having a restriction as recited in amended claim 33.

It is respectfully submitted that dependent claims 34-40 are patentable with independent claim 33 as set forth above. These dependent claims recite additional features that further distinguish the invention.

In view of the foregoing, Applicant respectfully submits that the pending claims are in condition for allowance and requests reconsideration of the application. The Examiner may telephone Applicant's undersigned counsel at the number below concerning this application.

Applicant also encloses a Petition for Extension of Time for three (3) months. Kindly charge this fee and any additional fees to Deposit Account No. 23-2405, Order No. 114474.00014.

WILLKIE FARR & GALLAGHER, LLP

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By: 

David D. Lee
Registration No. 51,929

WILLKIE FARR & GALLAGHER LLP
787 Seventh Ave.
New York, New York 10019
212-728-8674
212-728-9674 Fax